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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,934	04/21/2004	David G. Gorenstein	UTMB:1022	5106
34725 7590 03/23/2007 CHALKER FLORES, LLP 2711 LBJ FRWY Suite 1036 DALLAS, TX 75234			EXAMINER STEELE, AMBER D	
			ART UNIT	PAPER NUMBER
			1639	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/23/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/828,934

Applicant(s)

GORENSTEIN ET AL.

Examiner

Amber D. Steele

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 12-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/16&19/04;11/20/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Please note that the examiner for the present application has changed. However, the Technology Center (TC1600) and the Art Unit (AU1639) remain the same.

Status of the Claims

2. The amendment to the claims received on October 4, 2006 amended claim 7.

Claims 1-77 are currently pending.

Claims 1-11 are currently under consideration.

Election/Restrictions

3. Applicant's election of claims 1-11 in the reply filed on October 4, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted that applicants' amendment to claim 7 alters the original groups as set forth in the restriction requirement mailed on August 4, 2006. Group I is drawn to an aptamer that binds to a TGF-beta protein and includes SEQ ID NO: 62.

4. Claims 12-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 4, 2006.

Rejoinder

5. Restriction between product and process claims was required. The applicant elected claims directed to a product. If a product claim is subsequently found allowable, **withdrawn process claims that depend from or otherwise include all the limitations of the allowable**

product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the **amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996. Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to a rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Information Disclosure Statement

6. The information disclosure statement filed July 19, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. A copy of WO 00 47774 A1 has not been received.

7. The information disclosure statement (IDS) submitted on July 16, 2004; July 19, 2004; and November 20, 2006 are being considered by the examiner (see section 5 above).

Specification

8. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (please refer to page 30). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

9. The disclosure is objected to because of the following informalities: the priority data listed in the Declarations submitted on August 2, 2004 and October 8, 2004 is not listed in the first line of the specification.

Appropriate correction is required.

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

11. Claim 7 objected to because of the following informalities: SEQ ID NOS: 62 should be SEQ ID NO: 62 and “comprises one or more thio-modifications as set forth in SEQ ID NOS: 62” should be “comprising the nucleotide sequence of SEQ ID NO: 62”. Appropriate correction is required.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-6 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Pagratis et al. U.S. patent 6,346,611 issued February 12, 2002.

For present claims 1-6 and 8-11, Pagratis et al. teach aptamers that bind human TGFβ1, TGFβ2, and TGFβ2 dimers wherein the aptamers may comprise a labeling tag, phosphorothioate modifications, and/or be diluted in saline (i.e. pharmaceutically acceptable salts and diluent; please refer to entire specification particularly abstract; Figures; columns 1-2, 6-7, 10-13; Examples; Tables; claims 1-5). Regarding achiral aptamers, Pagratis et al. teaches various

Art Unit: 1639

aptamers without providing the secondary structure for each therefore the symmetry of the structures cannot be readily determined. Please refer to MPEP § 2112.01 which states “Where the claimed and prior art products are identical or substantially identical in structure or composition a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)”.

Therefore, the presently claimed invention is anticipated by the teachings of Pagratis et al.

14. Claims 1-6 and 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Pagratis et al. U.S. Patent 6,713,616 filed February 23, 2001.

For present claims 1-6 and 8-11, Pagratis et al. teach aptamers that bind to human TGFβ1, TGFβ2, and TGFβ2 dimers wherein the aptamers may comprise a labeling tag, phosphorothioate modifications, and/or be diluted in saline (i.e. pharmaceutically acceptable salts and diluent; please refer to entire specification particularly abstract; Figures; columns 1-2, 4, 6-8, 10-14; Examples; Tables; claims 1-14). Regarding achiral aptamers, Pagratis et al. teaches various aptamers without providing the secondary structure for each therefore the symmetry of the structures cannot be readily determined. Please refer to MPEP § 2112.01 which states “Where the claimed and prior art products are identical or substantially identical in structure or

Art Unit: 1639

composition a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)”.

Therefore, the presently claimed invention is anticipated by the teachings of Pagratis et al.

15. Claims 1 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Rubenfield et al. U.S. patent 6,551,795 filed February 18, 1999.

For present claims 1 and 7, Rubenfield et al. teach phosphothioate modified nucleic acids with less than 40% homology to present SEQ ID NO: 62 (please refer to the entire specification and SCORE results).

Therefore, the presently claimed invention is anticipated by the teachings of Rubenfield et al.

Allowable Subject Matter

16. The exact sequence of SEQ ID NO: 62 was not found in the prior art. An independent claim drawn to a partially thio-modified aptamer comprising the nucleic acid of SEQ ID NO: 62 would be free of the prior art.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ADS
March 12, 2007


MARK L. SHIBUYA
PRIMARY EXAMINER